Notice of Allowability	Application No.	Applicant(s)	
	10/085,142	GLANOWSKI ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2-20-2007*.

2. ☒ The allowed claim(s) is/are *42-57*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Scott Balderston on 26 April 2007.

The application has been amended as follows:

a. In claim 42 (i) on page 3 of the amended claims of 2 February 2007, after "results"; insert - - to a user or database. - -;

b. In claim 42 (f) on page 3 of the amended claims of 2 February 2007, after "determining"; replace "if" with - - that - -;

c. In claim 42 (g) on page 3 of the amended claims of 2 February 2007, delete "if the angular difference value of at least one of the ordered set of angular values is determined to differ from one previous angular value by at least the predetermined difference threshold, determining at least one category-dividing angular value based on the at least one of the ordered set of angular values" and replace with - - determining at least one category-dividing angular value based on the at least one ordered set of angular values, for the at least one of the ordered set of angular values that is determined in step (f) to have an angular difference value that differs from one previous angular value by at least the predetermined difference threshold - -;

d. Cancel claim 58.

The following is an examiner's statement of reasons for allowance: In the art, high throughput genotypic data is commonly obtained through the use of a pair of differently labeled fluorescent allele specific probes which in an ideal setting produce either fluorescence signal from either the combination of probes indicating heterozygousity or each probe signally indicating homozygosity. The data thus obtained is plotted as a scatter plot to aid in the identification of the allelic state. The independent claim is distinguished from the prior art by a non-statistical method for the identification alleles from clustered genotypic fluorescence. The method converts the position of genotypic fluorescence data in a scatter plot into an ordered list of angular values, determining the difference between successive values in the list, monitoring the difference for the occurance of a difference that is larger than a predetermined threshold that indicates the separation between different allelic data clusters. The art teaches as in Mein et al (Genome Research, Vol. 10, No. 3, p. 330-343, 2000)[cited as reference 01 in the Information disclosure statement filed 06 October 2004] the plotting of genotyping fluorescence data in the for of a scatter plot and the calculation an angular value as the ratio of intensity of different probes, but does not teach determining the identification of a difference values or category-dividing value. It is standard in the art to use statistical methods such as PCA , K-means, and normal mixture models to identify clusters in genotypic data. The instantly claimed method is closest to the method of hierarchal clustering developed by King (Jour. Am. Stat. Assoc., Vol. 69, p. 86-101,

March 1967). King considers each data point in a scatter plot to be an individual cluster. Each point is compared to every other point to generate a matrix of differences. Once all the data have been compared in a pairwise fashion, the matrix is scanned for comparisons that have the smallest difference value using a minimization function and those points are grouped as belonging to the same cluster. The process is iterated until all the data points have grouped or classified. Similarly, with regards to the comparison step of King, the instantly claimed method employs the use of a difference value. However distinguishing it self from the method of King, the instantly claimed method eliminates the need for pairwise comparisons over the entire data set through the use of a sorted data set, only comparing sequential values in the sorted data. The instant method is further distinguished from King by using a predetermined difference threshold to identify the clusters in the data. Thus the instantly claimed method is distinct from the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.S. Brusca 30 Aug 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER

/Karlheinz R. Skowronek/